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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/044,696	03/18/1998	GAIL BARCHFELD	1393.002	8826

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/20/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/044,696

Applicant(s)

BARCHFELD ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 25-43 ~~is/are~~ are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19 and 25-31 ~~is/are~~ are allowed.
- 6) ☒ Claim(s) 32-43 ~~is/are~~ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 39.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 04/25/03 (paper no. 38) in response to the Office Action mailed 10/22/02 (paper no. 34).

Status of Claims

- 2) Claim 19 has been amended via the amendment filed 04/25/03.
Claim 21 has been canceled via the amendment filed 04/25/03.
New claims 31-43 have been added via the amendment filed 04/25/03.
Claims 1-19 and 25-43 are pending in this application.
Claims 19 and 25-43 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Information Disclosure Statement

- 5) Acknowledgment is made of Applicants' information disclosure statement filed 04/25/03 (paper no. 39). The information referred to therein has been considered and a signed copy is attached to this Office Action (paper no. 40).

Objection Withdrawn

- 6) The objection to the drawings made under 37 C.F.R. 1.84 in paragraph 7 of the Office Action mailed 08/04/99 (paper no. 10) and maintained in paragraph 4 of the Office Action mailed 04/25/00 (paper no. 15) is withdrawn in light of Applicants' submission of formal drawings. These drawings have been approved by the draftsperson.

Objection(s) Maintained

- 7) The objection to the specification made under 35 U.S.C. § 132 in paragraph 8 of the

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Office Action mailed 10/22/02 (paper no. 34) with regard to the addition of new matter to the specification is maintained for reasons set forth therein and herebelow.

Applicants argue that the added information does not in any way go beyond the subject matter originally filed. Applicants contend that the sequence now presented in Figure 3 was publicly available on GenBank at the time of filing. Applicants state that the originally filed Figure 1A and 1B and claims disclose a sequence of LT containing alanine at residue 72. Applicants acknowledge that there are differences between the sequences presented originally and those in Figure 3, but submit that sequence errors are a common problem in molecular biology. Applicants assert that any discrepancies in sequence between original Figure 1 and added Figure 3 fall under the category of 'minor errors' and do not rise to the level of new matter.

Applicants' arguments have been carefully considered, but are non-persuasive. The sequence presented via Figure 3 was **not** a part of the specification, as originally filed. Applicants are correct in that Figure 1 discloses an LT containing alanine at residue 72. However, the Figure that is at issue is not Figure 1, but Figure 3. The fact that an amino acid sequence of a protein was known in the art prior to the invention is irrelevant. Except for the amino acid sequence depicted in Figure 1, what was publicly known was not a part of the instant specification, as originally filed. Attempts of bringing in new matter into the specification based on the sequence errors or discrepancies in sequence databases is improper. The rejection stands.

Rejection(s) Moot

- 8) The rejection of claim 21 made in paragraph 12 of the Office Action mailed 10/22/02 (paper no. 34) under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is moot in light of Applicants' cancellation of the claim.
- 9) The rejection of claim 21 made in paragraph 13 of the Office Action mailed 10/22/02 (paper no. 34) under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

Rejection(s) Withdrawn

- 10) The rejection of claims 19 and 25-30 made in paragraph 12 of the Office Action mailed 10/22/02 (paper no. 34) under 35 U.S.C. § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn upon further consideration. The term 'detoxified mutant' in the

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instant claims is interpreted as not being equivalent to 'non-toxic mutant', but to 'less toxic mutant' or 'mutant of reduced toxicity'.

11) The rejection of claims 19 and 25-30 made in paragraph 13 of the Office Action mailed 10/22/02 (paper no. 34) under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

New Rejection(s)

Applicants are asked to note the new rejection(s) made in this Office Action. Applicants' amendments and submission of new claims, necessitated the new ground(s) of rejection presented in this Office Action.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

12) Claims 37-43 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Instant new claims include limitations, such as: "streptococcal antigen."; "A antigen."; "B antigen..."; and "C antigen...". Applicants point to lines 14-23 on page 19 of the specification as providing descriptive support for the limitations. However, a review of this part of the specification shows that there is no descriptive support for the now included limitations. Therefore, the new limitation in the instant claims is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P. 608.04 to 608.04(c).

Applicants are invited to point to specific line and page numbers of the specification, as originally filed, that provide descriptive support for the limitations identified above, or to remove the new matter from the claim(s).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

13) Claims 32-43 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as

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the invention.

(a) Claim 37 is vague, indefinite and confusing in the recitation: 'meningococcus A antigens', 'meningococcus B antigens' and 'meningococcus C antigens', because it is unclear whether or not letters A, B and C refer to antigens of meningococcus, strain designations or serogroups of meningococcus.

(b) Analogous criticism applies to claims 41-43.

(c) Claims 32 and 35 are vague and indefinite in the use of abbreviation(s) in the claim language: 'HSV'; 'HIV'; 'CMV'; 'HCV'; 'HDV'; 'HAV'; 'EBV'; 'VZV'; and/or 'RSV', because it is unclear what do these abbreviations stand for. It is suggested that Applicants use the full terminology at first occurrence with the abbreviation retained within the parentheses.

(d) Claims 33-36 and 38-43, which depend directly or indirectly from claim 32 or 36, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

14) Claims 32-43 stand rejected. Claims 19 and 25-31 include allowable subject matter.

In claims 25-30, for proper antecedence, it is suggested that Applicants replace the recitation 'A method according to claim ...' with --The method according to claim--.

15) Applicants' amendments necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

16) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile

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transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The TC 1600 facsimile center receives transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347 until January 2004 and (571) 272-0854 beginning February 2004. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER